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Customer Number

**24024**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Liu et al.

Serial No. 10/596,062

Filed: May 26, 2006

For: **POLYMORPHIC CD24  
GENOTYPES THAT ARE  
PREDICTIVE OF MULTIPLE  
SCLEROSIS RISK AND  
PROGRESSION**

) Examiner: not yet assigned

) Art Unit: not yet 1634

) Customer No.: 24024

) Confirmation No.: 1364

) Attorney Docket No.: 22727/04398

Mail Stop Amendment

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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B forms and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

**FOREIGN LANGUAGE DOCUMENTS**

- ☐ In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication from a foreign patent office in a counterpart application citing such documents, together with an English-language version (if not already included) of that portion of the Communication indicating the degree of relevance found by the foreign patent office.
- ☐ In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant submits the following explanations:
- 
- ☐ Complete English translations of foreign language documents are being submitted herewith, and therefore no concise explanation for such documents is required.

**CERTIFICATION AND FEE PAYMENT INFORMATION**

- ☒ The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination under 37 C.F.R. § 1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. 03-0172, order number 22727/04398**.
- ☐ The present Information Disclosure Statement is being filed thirty days or fewer from a Communication from a foreign patent office and Applicant submits the following Statement Under 37 C.F.R. § 1.704(d). Each item of information contained in the Information Disclosure Statement was cited in a Communication from a foreign patent office in a counterpart application and this Communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☐ The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant submits the following Statement under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required. If this is not the case, the patent office is hereby authorized to charge any related fee to **Deposit Account No. \_\_\_\_\_**.
- ☐ Each item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign

application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this statement.

- ☐ The present Information Disclosure Statement is being filed (without a Statement under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier). Accordingly, Applicant submits the fee required under 37 C.F.R. § 1.17(p). The fee is being paid in the following manner:

- ☐ A check is attached in the amount of \$180.00 as required under 37 § 1.17(p).
- ☐ The patent office is hereby authorized to charge the amount of \$\_\_\_\_\_ and any related fee to **Deposit Account No.** \_\_\_\_\_.

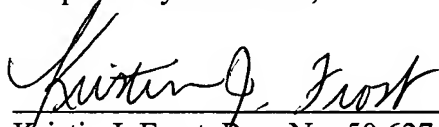
- ☐ The present Information Disclosure Statement is being filed after the mailing of a final Office Action, Notice of Allowance or an action that otherwise closes prosecution in the application, but on or before the payment of the issue fee. Accordingly, Applicant submits the following Statement under 37 C.F.R. § 1.97(e) along with the fee required under 37 C.F.R. § 1.17(p).

- ☐ Each item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a Communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

AND, the fee is being paid in the following manner:

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- ☐ The patent office is hereby authorized to charge the amount of \$\_\_\_\_\_ and any related fee to **Deposit Account No.** \_\_\_\_\_.
- ☒ **Please charge any fee deficiency or credit any overpayment to Deposit Account No. 03-0172, order number 22727/04398.**

Respectfully submitted,

  
\_\_\_\_\_  
Kristin J. Frost, Reg. No. 50,627  
Telephone: (216) 622-8895  
Customer No. 24024



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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/596,062		
		Filing Date	May 26, 2006		
		First Named Inventor	Liu et al.		
		Art Unit	not yet assigned		
		Examiner Name	not yet assigned		
Sheet	2	of	10	Attorney Docket Number	22727/04398

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Aigner, S., et al., "CD24, a mucin-type glycoprotein, is a ligand for P-selectin on human tumor cells," Blood 89: (9) 3385-3395 (May 1, 1997).	
		Bai, XF et al "The heat-stable antigen determines pathogenicity of self-reactive T cells in experimental autoimmune encephalomyelitis" J Clin Invest 105 No 9, 1227-32 May 2000	
		Barany, "Genetic Disease Detection and DNA Amplification Using Cloned Thermostable Ligase," Proc. Natl. Acad. Sci. USA, 88: 189-193 (Jan. 1991).	
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		Carter and Rodriguez, "Immunosuppressive treatment of Multiple Sclerosis," Mayo Clinic Proc. 64: 664 (1989).	
		Carton, H., et al., "Risks of Multiple Sclerosis in relatives of patients in Flanders, Belgium," J Neurol Neurosurg Psychiatry 62:329-33 (1997).	
		Collins, "Positional Cloning: Let's not call it reverse anymore" Nature Genetics 1: 3-6 (Apr. 1992).	
		De Bruijn, ML, et al "Induction of heat-stable antigen expression by phagocytosis is involved in in vitro activation of unprimed CTL by macrophages" J Immunol 156:2686-92 1996	
		Donis-Keller, et al., "A genetic linkage map of the human genome," Cell 51:319-337 (Oct. 23, 1987).	
		Ebers, G. C., et al., "A population-based study of multiple sclerosis in Twins", N Engl J Med 315, 1638-42 (Dec. 25, 1986).	

Examiner Signature		Date Considered	
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Sheet	3	of	10	Attorney Docket Number	22727/04398

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		Ebers, G. C., et al., "A full genome search in multiple sclerosis," Nat Genet 13:472-6 (Aug. 1996).	
		Eckert, et al., "DNA polymerase fidelity and the polymerase chain reaction," PCR Methods and Applications 1:17-24 (1991).	
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		(continued from line above) Eng 11 (12) 1155-61 (1998).	
		Englund, P. T., "The Structure and Biosynthesis of Glycosyl Phosphatidylinositol Protein Anchors", Annu Rev Biochem 62:121-38 (1993).	
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		Fischer, GF et al "Signal transduction in mymphocytic and myeloid cells via CD24, a new member of phosphoinositol-anchored membrane molecules" J Immun 144:638-641, 01/15/1990	
		Gasparini, et al., "Restriction site generating-polymerase chain reaction (RG-PCR) for the probless detection of hidden genetic variation: application to the study of some	
		(continued from line above) common cystic fibrosis mutations," Mol. Cell Probes 6: 1-7 (1992).	
		Gene Bank Accession: NM_013230, 12/03/2006, 4 pgs.	

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		Filing Date	May 26, 2006		
		First Named Inventor	Liu et al.		
		Art Unit	not yet assigned		
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Sheet	4	of	10	Attorney Docket Number	22727/04398

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		Gibbs, "Detection of single DNA base differences by competitive oligonucleotide priming," Nucleic Acid Res. 17 (7) :2437-2448 (1989).	
		Guatelli, et al, "Isothermal, In Vitro Amplification of Nucleic Acids by a Multienzyme Reaction Modeled After Retroviral Replication" Proc Natl Acad Sci, USA 87:1874-78 (1990)	
		Hahne, M. , et al., "The Heat-stable Antigen Can Alter Very Late Antigen 4-mediated Adhesion", J Exp Med 179:1391-5 (Apr. 1994).	
		Haines, J. L., et al., "A complete genomic screen for multiple sclerosis underscores a role for the major histocompatibility complex", Nat Genet 13:469-71 (Aug. 13, 1996).	
		Haines, J. L. , et al., "Linkage of the MHC to familial multiple sclerosis suggests genetic heterogeneity", Hum Mol Genet 7 (8): 1229- 34 (1998).	
		Hough, M.R., et al., "Mappig of CD24 and homologous sequences to multiple chromosomal loci" Genomics 22: 154-161 (1994).	
		Hubbe, M. et al., "Heat-Stable Antigen/CD24 on mouse T lymphocytes: evidence for a costimulatory function," Eur J Immunol 24:731-737 (1994).	
		Kellar-Wood, H. F. , et al., "Multiple Sclerosis and the HLA-D region: linkage and association studies," J Neuroimmunol 58:183-90 (1995).	
		Kerem, et al., "Identification of the cystic fibrosis gene: genetic analysis," Science 245:1073-1080, (Sept. 8, 1989).	
		Kuokkanen, S., et al, "A putative vulnerability locus to multiple sclerosis maps to 5p14-p12 in a region syntenic to the murine locus Eae2", Nat Genet 13:477-80 (Aug. 13, 1996)	

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/596,062
Filing Date	May 26, 2006
First Named Inventor	Liu et al.
Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	22727/04398

Sheet 5

of

10

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		Kurtzke, J. F. "Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS)," Neurology 33:1444-1452 (Nov. 1983).	
		Kurtzke, "Clinical definition for multiple sclerosis treatment trials," Ann. Neurol. 36:S73-S79, (1994).	
		Kwoh, et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead- based sandwich hybridization format", Proc.	
		(continued from line above) Natl. Acad. Sci. USA 86:1173-1177 (Feb. 1989).	
		Landegren, U., et al., "A ligase-mediated gene detection technique," Science 241:1077-1080 (Aug. 26, 1988).	
		Lander, et al., "Strategies for Studying Heterogeneous Genetic Traits in Humans by Using a Linkage Map of Restriction Fragment Length Polymorphisms," Proc. Natl. Acad. Sci.	
		(continued from line above) USA 83:7353-7357 (Oct. 1986).	
		Lander, et al., "Construction of multilocus genetic linkage maps in humans," Proc. Natl. Acad. Sci. USA 84:2363-2367 (Apr. 1987).	
		Lander, et al., "Mapping Mendelian Factors Underlying Quantitative Traits Using RFLP Linkage Maps," Genetics 121:185-199 (Jan. 1989).	
		Lathrop, "Strategies for Multilocus linkage analysis in humans," Proc. Nat. Acad. Sci. USA 81:3443-3446 (Jun. 1984).	

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		Filing Date	May 26, 2006
		First Named Inventor	Liu et al.
		Art Unit	not yet assigned
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Sheet 6	of 10	Attorney Docket Number	22727/04398

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		Liu, Y., et al., "Co-stimulation of murine CD4 T cell growth: cooperation between B7 and heat-stable antigen", Eur J Immunol 22:2855-2859 (1992).	
		Liu, Y., et al., "Heat-stable Antigen is a Costimulatory Molecule for CD4 T Cell Growth", J. Exp. Med. 175:437-45 (Feb. 1992).	
		Liu, Y., et al., "Distinct Costimulatory Molecules are Required for the Induction of Effector and Memory Cytotoxic T Lymphocytes," J Exp Med 185 (2): 251- 62 (Jan. 20, 1997).	
		Liu, X., et al., "B7H Costimulates Clonal Expansion of, and Cognate Destruction of Tumor Cells by, CD8+T Lymphocytes in Vivo," J. Exp. Med. 194 (9):1339-1348 (Nov. 5, 2001).	
		Martin, E. R., et al., "A Test for Linkage and Association in General Pedigrees: The Pedigree Disequilibrium Test," Am J Hum Genet 67:146-54 (2000).	
		Mattila, et al, "Fidelity of DNA synthesis by the Thermococcus litoralis DNA polymerase-an extremely heat stable enzyme with proofreading activity" Nucleic Acids Res 19 (1991)	
		McDonald, et al. "Are magnetic resonance findings predictive of clinical outcome in therapeutic trials in multiple sclerosis? The dilemma of interferon-beta," Ann. Neurol.	
		(continued from line above) 36:14-18 (1994).	
		McDonald, W. I., et al., "Recommended Diagnostic Criteria for Multiple Sclerosis: Guidelines from the International Panel on the Diagnosis of Multiple Sclerosis," Ann Neurol.	
		(continued from line above) 50:121-7 (2001).	

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		McKusik, V.A., CD24 Antigens; CD24, OMIM Online Mendelian Inheritance in Man, available at: <a href="http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=600074">http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=600074</a> (created 8/4/1994, last	
		(continued from line above) updated 6/14/2006), 3 pgs.	
		Miller, D. H. , et al. "Class II HLA antigens in multiple sclerosis," J Neurol Neurosurg Psychiatry 52:575-7 (1989).	
		Mitchell, "Update on Multiple Sclerosis Therapy", Cont. Clin., Neurol. 77 (1): 231-249 (Jan. 1993).	
		Monaco, et al., "Detection of deletions spanning the Duchenne muscular dystrophy locus using a tightly linked DNA segment," Nature 316:842-845, Aug. 29 1985.	
		Morling, N., et al., "Immunogenetics of multiple sclerosis and optic neuritis: DNA polymorphism of HLA class II genes," Immunogenetics 35:391-4 (1992).	
		Nickerson, D.A., et al., "Automated DNA diagnostics using an ELISA-based oligonucleotide ligation assay," Proc. Natl. Acad. Sci. USA, 87:8923-8927 (Nov. 1990).	
		Noseworthy, J. H. "Progress in determining the causes and treatment of multiple sclerosis," Nature 399 Supp., A40-47 (Jun. 24, 1999).	
		Okamoto, M., et al., "Heterogeneous Expressions of GPI-Anchored Proteins by Granulocytes from Patients with Aplastic Anemia (AA) and Myelodysplastic Syndrome (MDS)," Journal	
		(continued from line above) Blood 100 (11); No. 3508, ABSTRACT ONLY (Nov. 16, 2002).	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/596,062
Filing Date	May 26, 2006
First Named Inventor	Liu et al.
Art Unit	not yet assigned
Examiner Name	not yet assigned
Attorney Docket Number	22727/04398

Sheet 8

of

10

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Olerup, O. et al. "HLA class II-associated genetic susceptibility in multiple sclerosis: a critical evaluation," Tissue Antigens 38:1-15 (1991).	
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Sheet 9	of 10	Attorney Docket Number	22727/04398

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		Spielman, R. S. et al. "A Sibship Test for Linkage in the presence of association: The Sib Transmission/Disequilibrium Test," Am J Hum Genet 62:450-8 (1998).	
		Tobe, et al., "Single-well genotyping of diallelic sequence variations by a two-color ELISA-based oligonucleotide ligation assay," Nucleic Acids Res. 24 (19): 3728-3732 (1996)	
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